



Case No.: 04-218 (400.148)

## DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

### RNA INTERFERENCE MEDIATED INHIBITION OF INTERCELLULAR ADHESION MOLECULE (ICAM) GENE EXPRESSION USING SHORT INTERFERING NUCLEIC ACID (siNA)

the specification of which is attached hereto unless the following space is checked:

☒ was filed on March 15, 2004 as United States Application Serial Number 10/800,487.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s):

	<u>Number</u>	<u>Country</u>	<u>Day/Month/Year Filed</u>
1.			
2.			

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

	<u>Application Number</u>	<u>Filing Date</u>
1.	60/358,580	02.20.02
2.	60/363,124	03.11.02
3.	60/386,782	06.06.02
4.	60/406,784	08.29.02
5.	60/408,378	09.05.02
6.	60/409,293	09.09.02
7.	60/440,129	01.15.03

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

	<u>Application Number</u>	<u>Filing Date</u>	<u>Status: patented, pending, abandoned</u>
1.	10/427,160	04.30.03	Pending
2.	10/444,853	05.23.03	Pending

3.	10/693,059	10.23.03	Pending
4.	10/720,448	11.24.03	Pending
5.	10/757,803	01.14.04	Pending
6.	PCT/US03/05346	02.20.03	Inactive
7.	PCT/US03/05028	02.20.03	Inactive
8.	PCT/US02/15876	05.17.02	Inactive

I hereby appoint the practitioners associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and I direct that all correspondence be addressed to that Customer Number.

Customer Number: **020306**

Principal attorney or agent: Lisa M.W. Hillman

Telephone number: 312-913-0001

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: James McSwiggen

Inventor's signature: \_\_\_\_\_

Date: 11/30/05

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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

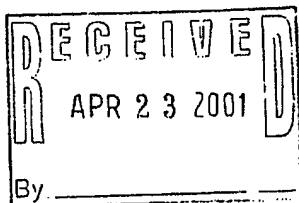
Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex parte KENNETH G. DRAPER

MAILED



Appeal No. 1996-1039  
Application No. 08/074,343

MAR 27 2001

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 3-10, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. An enzymatic RNA molecule which cleaves mRNA encoding transforming growth factor beta.

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The references relied upon by the examiner are:

Derynck et al. (Derynck), "Human transforming growth factor- $\beta$  complementary DNA sequence and expression in normal and transformed cells," Nature, Vol. 116, pp. 701-705 (1985)

Haseloff et al. (Haseloff), "Simple RNA enzymes with new and highly specific endoribonuclease activities," Nature, Vol. 334, pp. 585-591 (1988)

Kovacs, "Fibrogenic cytokines: the role of immune mediators in the development of scar tissue," Immunology Today, Vol. 12, No. 1, pp. 17-23 (1991)

Shah et al. (Shah), "Control of scarring in adult wounds by neutralising antibody to transforming growth factor  $\beta$ ," The Lancet, Vol. 339, pp. 213-214 (1992)

#### GROUND OF REJECTION<sup>1</sup>

Claims 1 and 3-10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Haseloff in view of Derynck and Kovacs.

Claims 1 and 3-10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Haseloff in view of Derynck and Shah.

We reverse

#### DISCUSSION

Haseloff teach general rules for the design of new RNA enzymes capable of highly specific RNA cleavage, and have successfully tested these RNA enzymes against target a sequence. See Haseloff, abstract. According to the

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<sup>1</sup> We note the examiner withdrew the rejection of claims 1 and 3-10 under 35 U.S.C. §§ 101, and 112, first paragraph. See Answer, ¶ 4. In addition, we note the examiner withdrew the rejection of claims 4-7 under 35 U.S.C. § 112, second paragraph in the Advisory Action mailed September 7, 1994 (Paper No. 10).

examiner (Answer<sup>2</sup>, page 4) "Haseloff et al. conclude that '[e]ssentially any RNA is a potential substrate for cleavage by a ribozyme. Provided that the transcribed sequences of the gene are known, it should be possible to target one or more ribozymes against specific RNA transcripts' (p. 591)." Although, Haseloff does not teach the claimed enzymatic RNA molecule that cleaves mRNA encoding transforming growth factor  $\beta$ , the examiner relies on Derynck to teach the DNA sequence of transforming growth factor  $\beta$ .

According to the examiner (Answer, page 5) "[o]ne of ordinary skill in the art would have been motivated to ... [combine Haseloff with Derynck], given the suggestions of Haseloff et al. concerning possible uses of ribozymes, and the knowledge that TGF- $\beta$  is involved in fibrous and connective tissue formation, and other important physiological functions as taught by Kovacs." Alternatively, the examiner argues (Answer, bridging paragraph, page 6-7) that "[i]t would have been obvious for one of ordinary skill in the art to make the claimed ribozymes in order to reduce scar tissue formation in healing wounds by suppressing TGF-  $\beta$  synthesis ... as taught by Shah et al."

However, we note appellant's argument (Paper No. 19<sup>3</sup>, page 2):

Kovacs in no way provides any discussion of the use of ribozymes but rather only proposes roles for TGF- $\beta$ . The statement that Kovacs concludes that "continued examination of the cellular and molecular events involved in the pathogenesis of fibrotic disorders is essential for the

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<sup>2</sup> Paper No. 16, mailed October 18, 1995.

<sup>3</sup> Received March 22, 1996.

development of strategies to suppress and/or eliminate fibrosis" indicates only that Kovacs desires more knowledge of the role TGF-  $\beta$ . It is a far step from indicating that ribozymes should be made to inhibit expression of TGF-  $\beta$  as presently claimed.

... Shah et al. is cited as teaching that reducing the amount of active TGF-  $\beta$  at a wound site reduces scar tissue formation. It discusses, however, only the effect of antibodies to TGF-  $\beta$  on the formation of scar tissue. It has nothing to do with ribozymes.

We remind the examiner, that in order to establish a prima facie case of obviousness, there must be more than the demonstrated existence of all of the components of the claimed subject matter. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the substitutions required. That knowledge cannot come from the applicants' disclosure of the invention itself.

Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).

On the record before us, we find no reasonable suggestion for combining the teachings of the references relied upon by the examiner in a manner which would have reasonably led one of ordinary skill in this art to arrive at the claimed invention. As explained by appellant neither the Kovacs or Shah reference relied upon by the examiner provides the reason or suggestion necessary to lead a



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